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Attorney Docket No. 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

PARIKH et al.

Group Art Unit: 1615

Application No. 09/281,430

Examiner: T. Ware

Filed: March 30, 1999

For: ANTICANCER COMPOSITIONS

INFORMATION DISCLOSURE STATEMENT

Mail Stop  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or*
- ☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

#### Copies of the References

- ☒ Copies of the references listed on the enclosed Form 1449 are enclosed herewith.
- ☐ A copy of the foreign search report is enclosed herewith.
- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status ( <i>check one</i> )		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

**Statement under 37 CFR 1.97(e)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No fee is owed by the applicant(s).
- ☐ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$ .
- ☐ Charge Deposit Account No. 12-1216 in the amount of \$ . (A duplicate copy of this communication is enclosed for that purpose.)

**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of PARIKH et al.  
Application No. 09/281,430

**Instructions as to Overpayment**

☒ Credit Account No. 12-1216.  
☐ Refund

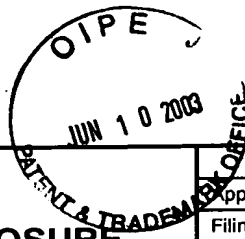
Respectfully submitted,

Shannon Schemel

Shannon Schemel, Reg. No. 47,926  
LEYDIG, VOIT & MAYER  
700 Thirteenth Street, N.W., Suite 300  
Washington, DC 20005-3960  
(202) 737-6770 (telephone)  
(202) 737-6776 (facsimile)

Date: June 10, 2003  
SDS:ves

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Compleat if Known</b>		
				Application Number	09/281,430	
				Filing Date	March 30, 1999	
				First Named Inventor	PARIKH	
				Group Art Unit	1615	
Examiner Name	T. Ware					
Attorney Docket Number	402076/SkyePharma					
Sheet	1	of	5			

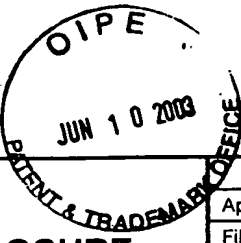
U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	1	4,970,076		Horrobin	11/13/90	
	2	5,342,625		Hauer et al.	8/30/94	
	3	5,364,632		Benita et al.	11/15/94	
	4	5,437,055		Wheatley, III	7/25/95	
	5	5,603,951		Woo	2/18/97	
	6	5,639,724		Cavanak	6/17/97	
	7	5,652,212		Cavanak et al.	7/29/97	
	8	5,696,153		Ainsworth et al.	12/9/97	
	9	5,929,030		Hamied et al.	7/27/99	
	10	6,004,573		Rathi et al.	12/21/99	
	11	6,284,268		Mishra et al.	9/4/01	

FOREIGN PATENT DOCUMENTS								
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	12 ✓	EP	314 060		Warner-Lambert Co.	5/3/89		
	13 ✓	EP	539 319		Novartis AG	4/28/93		
	14 ✓	EP	589 843		Sandoz AG	3/30/94		
	15 ✓	EP	636 618		Marigen S.A.	2/1/95		X+
	16 ✓	EP	670 715		Gattefosse S.A.	9/13/95		X+
	17 ✓	EP	760 237		CIPLA Ltd.	3/5/97		
	18 ✓	UK	2 217 173		B A Whittle	10/25/89		
	19 ✓	WO	94/08603		Smith-Kline Beecham Corp.	4/28/94		
	20 ✓	WO	94/08605		Smith-Kline Beecham Corp.	4/28/94		
	21 ✓	WO	94/23733		DR. Rentschler Arzenemittel GMBH & Co.	10/27/94		X+
	22 ✓	WO	94/25068		Sherman	11/10/94		
	23 ✓	WO	95/11039		Hexal Pharma GMBH	4/27/95		X+
	24 ✓	WO	95/33490		Enzon, Inc.	12/14/95		
	25 ✓	WO	96/13273		Sandoz Ltd.	5/9/96		
	26 ✓	WO	96/35415		Sime et al.	11/14/96		
	27 ✓	WO	97/00080		Hexal AG	1/3/97		X+
	28 ✓	WO	97/02042		GS Development AB	1/23/97		
	29 ✓	WO	97/12626		Dietl	4/10/97		X+
	30 ✓	WO	97/19692		Sandoz-Patent-GMBH	6/5/97		
	31 ✓	WO	97/22358		Sherman	6/26/97		
	32 ✓	WO	97/25977		Novartis AG	7/24/97		
	33 ✓	WO	97/26003		Galena A S	7/24/97		
	34 ✓	WO	97/36610		Chong Kun Dang Corp.	10/9/97		

Examiner Signature		Date Considered	
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- \* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).  
 + An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 5

### Complete if Known

Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	PARIKH
Group Art Unit	1615
Examiner Name	T. Ware
Attorney Docket Number	402076/SkyePharma

### OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
	35	Ardulno, M.J. et al., "Microbial Growth and Endotoxin Production in the Intravenous Anesthetic Propofol", Infection Control and Hospital Epidemiology, Vol. 12, No. 9, September 1991, pp. 535-539.		
	36	Attwood, David, "Microemulsions," Colloidal Drug Delivery Systems, © 1994, pp. 31-33.		
	37	Babl et al., "New Formulations of Propofol in an LCT/MCT Emulsion: Approach to Reduce Pain on Injection", Eur. Hosp. Pharmacy, January 1995, Vol. 1, No. 1, pp. 15-21.		
	38	Bennett et al., "Postoperative Infections Traced to Contamination of an Intravenous Anesthetic, Propofol", Natl. Ctr. for Infectious Diseases, Vol. 333, No. 3, (1999) pp. 2-9.		
	39	Cairns et al., "Tolerance of Mixed Lipid Emulsion in Neonates: Effect of Concentration", Archives of Disease in Childhood, (1996), Vol. 75, p. F113-F116.		
	40	Collins-Gold et al., "Parenteral Emulsions for Drug Delivery," Advanced Drug Delivery Reviews, (1990) Vol. 5, pp.189-208.		
	41	Cox et al., "Influence of Different Fat Emulsion-Based Intravenous Formulations on the Pharmacokinetics and Pharmacodynamics of Propofol," Pharmaceutical Research, (1998) Vol. 15, No. 3, pp. 442-48.		
	42	Crowther et al., "Growth of Microorganisms in Propofol, Thiopental and a 1:1 Mixture of Propofol and Thiopental", Anesth. Analg., (1996), Vol. 82, pp. 475-478.		
	43	De Sommer et al., "A Comparative Study on the Effects of Propofol in Emulsion and Intralipid® on Fat Metabolism," Acta Anesthesiologica Belgica, (1990) Vol. 41, No. 2, pp. 133-138.		
	44	Dewandre et al., "A Comparison of the 2% and 1% Formulations of Propofol During Anaesthesia for Craniotomy," Anesthesia, (1994), Vol. 49, pp. 8-12.		
	45	"Diprivan 1% Injection," Physicians' Desk Reference, 1996, pp. 2833-39.		
	46	"Diprivan 1% Injection," Physicians' Desk Reference, 1999, pp. 3411-18.		
	47	Doenicke, A.W. et al., "Pharmacokinetics and Pharmacodynamics of Propofol in a New Solvent", Anesth. Analg., (1997), Vol. 85, pp. 1399-403.		
	48	Doenicke, A.W. et al., "Reducing Pain During Propofol Injection: The Role of the Solvent", Anesth. Analg., (1996), Vol. 82, pp. 472-4.		
	49	Eddleston et al., "The Effect on Serum Lipid Concentrations of a Prolonged Infusion of Propofol - Hypertriglyceridaemia Associated with Propofol Administration," Intensive Care Med., (1991), Vol. 17, pp. 424-426.		
	50	Ewart et al., "Forum: 2% Propofol for Sedation in the Intensive Care Unit, A Feasibility Study", Anaesthesia, February 1992, Vol. 47, No. 2, pp. 146-148.		
	51	Freeman, Andrew B., "A Technique for Reducing Pain Associated with Propofol Administration," Anesth. Analg., 1992 (1 page).		

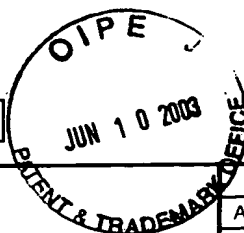
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Sheet	3	of	5	Application Number	09/281,430
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			Yes	No**
	52	Ghouri et al., "Effect of Flumazenil on Recovery after Midazolam and Propofol Sedation", Anesthesiology, (1994), Vol. 81, pp. 333-339.		
	53	Gottardis et al., Effect of Prolonged Sedation with Propofol on Serum Triglyceride and Cholesterol Concentrations, British J. Anaesthesia, (1989) Vol. 62, pp. 393-396.		
	54	King et al., "Lidocaine for the Prevention of Pain Due to Injection of Propofol", Anesth. Analg. (1992), Vol. 74, pp. 246-249.		
	55	Lindholm, Marianne, "Critically Ill Patients and Fat Emulsions," Minerva Anesthesiology, (1992), Vol. 58, No. 10, pp. 875-879.		
	56	Mangar et al., "Tourniquet at 50 mm Hg Followed by Intravenous Lidocaine Diminishes Hand Pain Associated with Propofol Injection", Anesth. Analg., (1992), Vol. 74, pp. 250-252.		
	57	Mirakhur et al., "Induction Characteristics of Propofol in Children: Comparison with Thiopentone", Anesthesia, (1998), Vol. 43, pp. 593-598.		
	58	Nichols, Ronald Lee, "Bacterial Contamination of an Anesthetic Agent," New Engl. J. Med., (1995), Vol. 333, No. 3, pp. 184-185.		
	59	Peereboom et al., "Successful Re-treatment with Taxol After Major Hypersensitivity Reactions", J. Clin. Oncology, Vol. 11 No. 5, 1993, pp. 885-890.		
	60	Sandstrom et al., "Structured Triglycerides Were Well Tolerated and Induced Increased Whole Body Fat Oxidation Compared With Long-Chain Triglycerides in Postoperative Patients", Journal of Parenteral and Enteral Nutrition, (1995), Vol. 19 No. 5, pp. 381-6.		
	61	Sharma et al., "Novel Taxol Formulations: Preparation and Taxation of Taxol-Containing Liposomes," Pharm. Res. Vol. 11 No. 6, 1994, pp.889-896.		
	62	Sklar, Grant E., "Propofol and Postoperative Infections," The Annals of Pharmacotherapy, (1997), Vol. 31, pp. 1521-3.		
	63	Smith et al., "Propofol: An Update on its Clinical Use," Anesthesiology, Oct. 1994, Vol. 81, No. 4, pp. 1005-1043.		
	64	Stark, et al., "A review of the safety and tolerance of propofol ('Diprivan')", Postgraduate Medical Journal, 1985, Vol. 61, Suppl. 3, pp. 152-156.		
	65	Stenz et al., "A new physiologically approached in vitro test for quick evaluation of the hemolytic activity of surfactants", Pharmazie, (1996), Vol. 51, No. 5, pp. 283-287.		
	66	Sosis et al., "Propofol, but not Thiopental, Supports the Growth of Candida albicans", Anesth. Anal., (1995), Vol. 81, pp. 132-134.		
	67	Tarr et al., "A New Parenteral Emulsion for the Administration of Taxol," Pharmaceutical Research, Vol. 2 No. 2, 1987, pp. 162-165.		

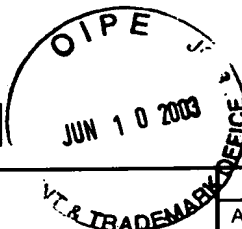
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Examiner Signature	Date Considered
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			Yes	No**
	68	Tessler et al., "Growth curves of <i>Staphylococcus aureus</i> , <i>Candida albicans</i> , and <i>Moraxella osloensis</i> in propofol and other media", Can. J. Anaesth. (1992), Vol. 39 No. 5, pp. 509-511.		
	69	White et al., "Sedative Infusions During Local and Regional Anesthesia: A Comparison of Midazolam and Propofol", J. Clin. Anesth., Jan/Feb 1991, Vol. 3, pp. 32-39.		
	70	Sosis, et al., Growth of <i>Staphylococcus aureus</i> in Four Intravenous Anesthetics, Anesth Analg (1993) Vol. 77, pp. 766-768.		
	71	Groves, et al., "The self-emulsifying action of mixed surfactants in oil", Acta Pharm. Suecica, Vol. 13, (1976), pp. 361-372.		
	72	Sharma, et al., "Novel Taxol® Formulation: Polyvinylpyrrolidone Nanoparticle-Encapsulated Taxol® for Drug Delivery in Cancer Therapy", Oncology Research, Vol. 8, Nos. 7/8, pp. 281-286, (1996).		
	73	Wheeler, et al., "Polyethylene Glycol Modified Phospholipids Stabilize Emulsions Prepared from Triacylglycerol", J. of Pharmaceutical Sciences, Vol. 83, No. 11, pp. 1558-1564, (Nov. 1994).		
	74	Lundberg, B., "Preparation of Drug-Carrier Emulsions Stabilized with Phosphatidylcholine-Surfactant Mixtures", J. of Pharmaceutical Sciences, Vol. 83, No. 1, pp. 72-75, (1994).		
	75	Sjöström, et al., "A Method for the Preparation of Submicron...and Surfactant Concentration", J. of Pharmaceutical Sciences, Vol. 82, No. 6, pp. 579-583, (June 1993).		
	76	Benita, et al., "Submicron Emulsions as Colloidal Drug...Physicochemical Characterization", J. of Pharmaceutical Sciences, Vol. 82, No. 11, pp. 1069-1079, (Nov. 1993).		
	77	Lundberg, B., "A Submicron Lipid Emulsion Coated with Amphipathic Polyethylene Glycol for Parenteral Administration of Paclitaxel (Taxol)", J. Pharm. Pharmacol., Vol. 49, pp. 16-21, (1997).		
	78	Adams, et al., "Taxol: A History of Pharmaceutical Development and Current Pharmaceutical Concerns", J. of the Natl. Cancer Inst. Monographs, No. 15, pp.141-147, (1993).		
	79	Terwogt, et al., "Alternative formulations of paclitaxel", Cancer Treatment Reviews, Vol 23, pp. 87-95, (1997).		
	80	Groves et al., "Rheological characterization of self-emulsifying oil/surfactant systems", Acta Pharm. Suecica, Vol. 13, pp. 353-360, (1976).		
	81	Eugster, et al., "Marigenol®-Concentrates comprising Taxol and/or Taxan esters as active substances", Panminerva Med., Vol. 38, pp. 234-242, (1996).		

Examiner Signature

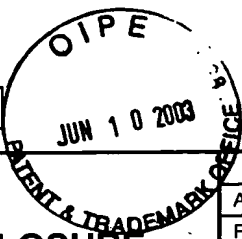
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